K132386

DEC 2 3 2013

200 West Ohio Avenue
Dover, OH 44622
(330) 364-0981

zimmer

Summary of Safety and Effectiveness

Sponsor:	Zimmer Surgical, Inc. 200 West Ohio Avenue Dover, OH 44622
Contact Person:	Allison Scott, RAC Senior Consultant Telephone: (317) 569-9500 x106 Fax: (317) 569-9520
Date:	August 1, 2013
Trade Name:	TotalShield™ Surgical Helmet System
Product Code / Device:	FYA – Surgical Gown
Regulation Number / Description:	21 CFR § 878.4040 – Surgical Apparel
Predicate Device:	Microtek Medical Freedomaire III Surgical Helmet System Model 10322STK, K102971, cleared 02/23/2011
Device Description:	The *TotalShield* Zippered Surgical Toga and/or *TotalShield* Surgical Hood are used with the *TotalShield* Surgical Helmet and/or *TotalShield* Advanced Surgical Helmet with LED lighting as the *TotalShield* Surgical Helmet System to provide a barrier between the operating environment and the surgical personnel in order to protect against contamination and/or exposure of infectious body fluids and harmful microorganisms. The *TotalShield* Surgical Helmet and Advanced Surgical Helmet with LED lighting have a battery powered fan, which provides a continuous flow of air in the *TotalShield* Surgical Hood or Zippered Surgical Toga. The *TotalShield* Surgical Hood is a stand-alone head cover that may be worn with a separate surgical gown, while the *TotalShield* Zippered Surgical Toga is a one-piece head and body cover.

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The stand-alone *TotalShield* Surgical Hood is identical to the hood that is incorporated into the *TotalShield* Zippered Surgical Toga. The *TotalShield* Surgical Hood or Zippered Surgical Toga must be worn over a *TotalShield* Surgical Helmet or Advanced Surgical Helmet with LED lighting.

The *TotalShield* Zippered Surgical Toga has been tested to meet the applicable AAMI PB70 standards for level 3 compliance. The AAMI standard does not cover apparel for the head, face, and eyes. Therefore, the hoods and lens are exempt from classification under the AAMI PB70:2003 standard.

Intended Use:

The *TotalShield* Zippered Surgical Toga and/or *TotalShield* Surgical Hood is for use with the *TotalShield* Surgical Helmet and/or *TotalShield* Advanced Surgical Helmet with LED lighting as the *TotalShield* Surgical Helmet System that is intended to be worn by surgical personnel to provide a barrier between the operating environment and the surgical personnel in order to protect against contamination and/or exposure of infectious body fluids and harmful microorganisms.

Technological Characteristics:

The *TotalShield* Surgical Helmet System is substantially equivalent to other legally marketed surgical apparel systems, specifically the Microtek Medical Freedomaire III Surgical Helmet System in that the devices have similar technological characteristics, including:

- Has the same intended use, target population and indications for use as the predicate
- Uses the same operating principles
- Incorporates the same basic design of durable helmet and single-use hoods and togas
- Hood and toga are sterilized using the same mode
- Both are sterilized to SAL of 10-6
- Reusable helmets are provided non-sterile
- Is manufactured of similar materials

Minor differences include:

- Adjustable length on the Toga

- Slight dimensional differences
- Optional LED lighting on Helmet

The minor differences do not affect the safety or effectiveness of the device and the *TotalShield* Surgical Helmet System is Substantially Equivalent to the predicate device.

Indications for Use

Property or Characteristic	Proposed Device *TotalShield* Surgical Helmet System	Predicate Freedomaire III Surgical Helmet System
Intended Use/ Indications for Use	The *TotalShield* Zippered Surgical Toga and/or *TotalShield* Surgical Hood is for use with the *TotalShield* Surgical Helmet and/or *TotalShield* Advanced Surgical Helmet with LED lighting as the *TotalShield* Surgical Helmet System that is intended to be worn by surgical personnel to provide a barrier between the operating environment and the surgical personnel in order to protect against contamination and/or exposure of infectious body fluids and harmful microorganisms.	The Freedomaire III Surgical Helmet System is intended to be worn by surgical personnel to provide a barrier between the operating environment and the surgical personnel in order to protect against contamination and/or exposure of infectious body fluids and harmful microorganisms.
Target Population	Operating room personnel	Operating room personnel

Technology & Product Features

Property or Characteristic	Proposed Device *TotalShield* Surgical Helmet System.	Predicate Freedomaire III Surgical Helmet System
***TotalShield* Zippered Surgical Toga and Surgical Hood**		
Adjustable length (Toga)	Tear away feature at the bottom of the toga (outside of the critical zone) removes 12" from the length	Length is not adjustable

Property or Characteristic	Proposed Device *TotalShield* Surgical Helmet System	Predicate Freedomaire III Surgical Helmet System
Recognized Consensus Standards	Compliant at level 3 Passed -AAMI/ANSI PB70:2003/(R)2009 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities Passed -ASTM F2407-06 Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities	Compliant at level 3 Passed -AAMI/ANSI PB70:2003/(R)2009 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities Passed -ASTM F2407-06 Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities
Sterility Assurance Level via EO Sterilization	10^{-6}	10^{-6}
Conditions of Use	Disposable/Single Use	Disposable/Single Use
Closure Feature	Toga features a neck tie and waist tie Hood pulls over the head and does not require security	Toga features a neck tie and waist tie Hood pulls over the head and does not require security
Toga Sizes	Regular, Large, Extra Large	Regular, Large, Extra Large
Color	Blue	Blue
***TotalShield* Surgical Helmet and Advanced Surgical Helmet with LED lighting**		
Method of Hood Attachment	Mechanical slot and hook-and-loop	Male features molded into faceshield mate with female interface on helmet
Lighting Option	LED	None

Materials

Property or Characteristic	Proposed Device *TotalShield* Surgical Helmet System	Predicate Freedomaire III Surgical Helmet System
Toga and Hood	Nonwoven fabric	Nonwoven fabric
Lens/Face Shield	PETG clear copolyester	Clear polycarbonate

Property or Characteristic	Proposed Device *TotalShield* Surgical Helmet System	Predicate Freedomaire III Surgical Helmet System
Filter	Blended Synthetic Fiber Spunbound Polypropylene	Blended Synthetic Fiber Spunbound Polypropylene
Helmet	Plastic	Plastic
LED Components	Aluminum, Stainless Steel	Not Applicable

Performance Data Summary

Property or Characteristic	Testing Method	Proposed Device *TotalShield* Surgical Helmet System	Predicate Freedomaire III Surgical Helmet System
***TotalShield* Zippered Surgical Toga and Surgical Hood**			
Flammability of Clothing Textiles	**ASTM F2100-07** reference 16 CFR-1610.4	Class 1 Compliant-pass	Compliant
Biological Evaluation on Skin Contacting Material	**ISO-10993-11** Acute Systemic Injection Test **ISO-10993-10** Intracutaneous Reactivity Test **ISO-10993-5** MEM Elution Assay with L-929 Mouse Fibroblast Cells **ISO-10993-10** Guinea Pig Maximization Sensitization Test	Compliant- pass	Compliant
Sterility Method	**ISO 11607-2** Packaging Validation **ISO 11135-1** EO Validation **ISO 10993-7** EO Residual Test	Compliant- pass	Compliant
Tear Resistance	**ASTM D5733** MD Trap Tear	Compliant- pass	AAMI Level 3
	ASTM D5733 CD Grab Tensile Strength	Compliant- pass	AAMI Level 3
Tensile Strength	**ASTM D5034** Grab Tensile Strength	Compliant- pass	AAMI Level 3
Seam Strength	Test method **ASTM D1683**	Compliant- passed seam test	AAMI Level 3
Lint	**ISO 9073; EN 13795-2** Test methods for surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment	Compliant- pass	AAMI Level 3

Property or Characteristic	Testing Method	Proposed Device *TotalShield* Surgical Helmet System	Predicate Freedomaire III Surgical Helmet System
Water Vapor Transmission Rate	Test method **ASTM D6701**	Compliant	AAMI Level 3
Water resistance: Impact penetration Hydrostatic pressure	**AAMI/ANSI PB70**	Compliant Level-3	Compliant Level-3
***TotalShield* Surgical Helmet and Advanced Surgical Helmet with LED lighting**			
Airflow Testing	Internal Fan Performance Test Method	Passed Acceptance Criteria	Passed Acceptance Criteria
Helmet Noise Testing	Internal Noise Measurement Test Method	Passed Acceptance Criteria	Passed Acceptance Criteria
Battery Life Testing	Internal Battery Performance Test Method	Passed Acceptance Criteria	Passed Acceptance Criteria

Performance Data:

Non-Clinical Performance:

During the development process of the *TotalShield* Surgical Helmet System, the following testing was completed:

Electrical safety and Environmental testing (IEC 60601-1 and IEC 60601-1-2)

Device Usability testing was conducted in accordance with requirements of IEC 60601-1-6 and IEC 62366:2007.

Sterilization Validation testing was conducted in accordance with AAMI/ANSI/ISO 11607-1, 11607-2 and AAMI/ANSI/ISO 11135-1. Shipping Validation was conducted according to ASTM D4169-09.

Biocompatibility Testing was conducted on skin contact material in accordance with ISO 10993-1, ISO 10993-10, ISO 10993-5 and ISO 10993-7.

Non-Clinical testing was conducted to demonstrate that the subject device performed as intended and met all acceptance criteria, including:

- Airflow Testing
- Helmet Noise Testing
- Battery Life Testing
- Liquid Barrier testing (per AAMI/ANSI PB70, for Surgical Zippered Toga only)

The *TotalShield* Surgical Helmet System adheres to the specifications for requirements for performance, documentation, and labeling per ASTM F2407-06.

Clinical Performance:

Clinical data were not needed for this device.

Conclusion:

All tests passed according to predetermined acceptance criteria, thus demonstrating equivalent performance of the subject device to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 23, 2013

Zimmer Surgical, Incorporated
C/O Allison Scott, RAC
Regulatory Affairs Consultant
Navigant Consulting, Incorporated
9001 Wesleyan Road, Suite 200
Indianapolis, IN 46268

Re: K132386
Trade/Device Name: TotalShield™ Surgical Helmet System
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Gown
Regulatory Class: II
Product Code: FYA
Dated: November 21, 2013
Received: November 22, 2013

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

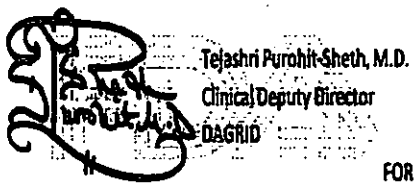
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132386

Device Name
TotalShield Surgical Helmet System

Indications for Use *(Describe)*
The TotalShield Zippered Surgical Toga and/or TotalShield Surgical Hood is for use with the TotalShield Surgical Helmet and/or TotalShield Advanced Surgical Helmet with LED lighting as TotalShield Surgical Helmet System that is intended to be worn by surgical personnel to provide a barrier between the operating environment and the surgical personnel in order to protect against contamination and/or exposure of infectious body fluids and harmful microorganisms.

00990000100 TotalShield Surgical Helmet (Non-sterile, Reusable)
00990000200 TotalShield Advanced Surgical Helmet with LED Lighting (Non-sterile, Reusable)
00990020000 TotalShield Six Bay Smart Batter Charger and Calibration System (Non-sterile, Reusable)
00990020002 TotalShield Two Bay Smart Battery Charger and Calibration System (Non-sterile, Reusable)
00990010200 TotalShield Rechargeable Li-Ion Battery (Non-sterile, Reusable)
00990010300 TotalShield Rechargeable Extended Life Li-Ion Battery (Non-sterile, Reusable)
00990030112 TotalShield Surgical Hood Sterile, EO Single Use
00990031210 TotalShield Zippered Sugical Toga AAMI Level 3 X-Large (Sterile (EO), Single Use)
00990031110 TotalShield Zippered Sugical Toga AAMI Level 3 (Sterile (EO), Single Use)
00990031010 TotalShield Zippered Sugical Toga AAMI Level 3 (Sterile (EO), Single Use)
00990000306 TotalShield Surgical Helmet Rear Cranial Support (Non-sterile, Reusable)
00990010400 TotalShield Battery Holster (Non-sterile, Reusable)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Sreekanth Gutala -S

Digitally signed by Sreekanth Gutala -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000564490, cn=Sreekanth Gutala -S
Date: 2013.12.23 13:08:42 -05'00'